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| 10/526,787 | 12/12/2005 | Koji Hasegawa | JCLA16283 | 7885 |
| J C Patents Suite 250 4 Venture Irvine, CA 92618 | 7550 01/23/2009 | | EXAMINER EDWARDS, LAURA ESTELLE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,787

Applicant(s)

HASEGAWA ET AL.

Examiner

Laura Edwards

Art Unit

1792

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10 and 12-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25, 26 and 28 is/are allowed.
- 6) ☒ Claim(s) 1-6, 15-22, 27 and 29 is/are rejected.
- 7) ☒ Claim(s) 8-10, 12-14, 23 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20081015
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

35 USC § 112 Sixth Paragraph

Acknowledgement is made of claims 21 and 23-26 which include means plus function limitation(s) which do not invoke 35 U.S.C. 112 sixth paragraph because the claims describe the structure supporting the prescribed function. For example, “cooling means” describes structure effecting cooling while “heating means” describes structure effecting heating and “sealing means” describes structure to effect sealing.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 6, 15-17, 22, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohmeyer (2000DE-2002352) in view of Shuri et al (JP 2000-126580), hereinafter referred to as Shuri.

Mohmeyer provides a coating apparatus including a ventilated rotating drum or pan (1) in which granules (i.e., pharmaceuticals) to be processed are accommodated and which is driven to rotate around its axial line, and a ventilation mechanism (6, 9) wherein said rotating drum includes one end and the other end along the direction of the axial line and a peripheral wall that connects said one end and said other end, said other end being located with respect to a rotary drive mechanism (not shown) for driving said rotating drum, wherein said one end, said other end, and said peripheral wall at a whole configure a vessel for accommodating granules to be processed, said peripheral wall is bare has no air passage, said one end and said other end are respectively provided with an air vent opening, one (area 9) of which constitutes an air inlet for

supplying process gas from outside into said rotating drum, and the other one (area 15) of which constitutes an air outlet for exhausting the process gas from inside said rotating drum to the outside, said ventilation mechanism including a lower duct (6) with air/gas supply source (not shown) provided at the other end of said rotating drum for fluidly communicating the air vent openings, wherein the process gas supplied into said rotating drum through said constituted air inlet (9) via lower duct (6) would be passed through said layer of the granules inside said rotating drum to be exhausted from said air outlet. Mohmeyer is silent concerning 1) a casing for the entire apparatus and 2) the ventilation mechanism communicating with respect to an air duct at a first predetermined location. However, it was known in the art, at the time the invention was made, to fully encase or enclose a rotary coating drum and its parts therein as evidenced by Shuri (see Fig. 1). In light of Shuri, one of ordinary skill in the art would readily appreciate encasing or enclosing the Mohmeyer apparatus for reasoning including further insulating the apparatus, providing for a more aesthetically pleasing apparatus, to ensuring safety of the apparatus with the mechanisms covered to seal the apparatus and its parts from unwanted tampering. As for the ventilation mechanism communicating with an air duct, Mohmeyer does provide an additional duct (5) which is deemed in fluid communication with the ventilation mechanism such that one of ordinary skill in the art would expect that the additional duct (5) would be used to supply a fluid (i.e., whether liquid or gas such as air) so as to facilitate the coating of the granules.

With respect to claim 2, the axial line (8) of the rotating drum, defined by the combination above, is preset at zero degrees with respect to a horizontal line.

With respect to claim 4, one of ordinary skill in the art would expect the drum to oscillate or vibrate to some degree about the axial line of the drum as the drum rotates with the contents therein.

With respect to claim 6, axial line (8) of the drum aligns with air vent opening (9) which is at center of the rotating drum.

With respect to claims 15 and 16, the combined teachings of Mohmeyer and Shuri provide a coating apparatus including a ventilated rotating drum as mentioned previously and Mohmeyer also provides for a hollowed area (9) which would constitute a hollow drive shaft section of the drum but Mohmeyer does not teach discuss discharging granule products through the hollow section via ducting to enable discharging of granule products via the hollowed area. However, it was known in the art, at the time the invention was made, to provide a hollow drive shaft section (area 13) of a coating drum with ducting (22) therethrough to enable discharging of granule products via the hollowed area as evidenced by Shuri (see abstract and drawings). In light of the teachings of Shuri, one of ordinary skill in the art would readily appreciate the provision of ducting through the hollow drive shaft section of the apparatus as defined by the combination above as an alternative way to extract granule products from the drum whether the user is servicing the drum in the front or the rear of the drum.

With respect to claim 17, the drum is shaped such that it increases in diameter gradually to a center of the drum and then tapers toward the axial line (8). Neither Mohmeyer or Shuri suggest shaping of the drum as instantly claimed including an inclined part with respect to the axial line at a preset angle. However, shaping of the drum as desired to invoke further tumbling

action of the contents of the drum to effect more uniform coating of the contents is deemed to be within the purview of one skilled in the art.

With respect to claim 22, see the response to claim 17 with respect to the shaping of the drum being within the purview of one skilled in the art.

With respect to claim 27, the apparatus as defined by the combination above would meet all claimed limitations.

With respect to claim 29, the apparatus as structurally defined by the combination above would enable gas in fluid communication with the interior of the drum and any contents therein to be exposed to the processing gas in so long as a predetermined period of time is allowed to pass to enable the processing gas to fill the interior of the drum.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohmeyer (2000DE-2002352) and Shuri et al (JP 2000-126580) as applied to claims 1 and 2 above and further in view of Gross (JP43- 19511).

The teachings of Mohmeyer and Shuri have been mentioned above but neither teach or suggest the drum being angled or inclined. However, it was known in the art at the time the invention was made to provide a rotary drum with angle adjustment means (75) to enable the drum to be angled in a predetermined angle range to facilitate tumbling of the materials being coated therein as evidenced by Gross (see abstract and Fig. 1). It would have been obvious to one of ordinary skill in the art to provide the angle adjustment means as taught by Gross in the apparatus defined by the combination above in order to position the drum at a desired angle to facilitate tumbling of the materials being coated.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohmeyer (2000DE-2002352) and Shuri et al (JP 2000-126580) as applied to claim 1 above and further in view of Takei et al (US 5,507,868), hereinafter referred to as Takei.

The teachings of Mohmeyer and Shuri have been mentioned above but neither teach or suggest use of a porous part in communication with the air vent. However, it was known in the art at the time the invention was made to provide a rotary drum with porous part or louver(s) (48) in order to minimize turbulent flow of the gas supplied into the drum via the inlet as evidenced by Takei et al (col. 7, lines 6-24). It would have been obvious to one of ordinary skill in the art to provide the porous part or louver(s) as taught by Takei in the apparatus as defined by the combination above in order to minimize turbulent flow of the gas supplied into the drum via the inlet.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohmeyer (2000DE-2002352) and Shuri et al (JP 2000-126580) as applied to claim 1 above and further in view of Takahiro et al (JP7- 328408), hereinafter referred to as Takahiro.

The teachings of Mohmeyer and Shuri have been mentioned above but neither teach or suggest the drum including protruding baffling. However, it was known in the art, at the time the invention was made to provide appropriate baffling on the inner peripheral wall of the drum to facilitate tumbling of the granule material in the drum and thereby enhancing the coating of the granule material as evidenced by Takahiro (see baffling (18) in Fig. 1). In light of the teachings of Takahiro, it would have been obvious to one of ordinary skill in the art to provide appropriate

baffling on the inner peripheral wall of the drum of the apparatus as defined by the combination above in order to facilitate to tumbling and uniform coating of the granule material in the drum.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohmeyer (2000DE-2002352) and Shuri et al (JP 2000-126580) as applied to claim 1 above and further in view of Arami et al (JP 62- 294461), hereinafter referred to as Arami.

The teachings of Mohmeyer and Shuri have been mentioned above but neither teach or suggest a heat exchanger for the drum to heat or cool the drum. However, it was known in the art, at the time the invention was made, to provide a heat exchanger in communication with the drum in order to provide temperature control of the coating process in the drum as evidenced by Arami (see abstract). It would have been obvious to one of ordinary skill in the art to provide a heat exchanger as taught by Arami in communication with the drum of the apparatus defined by the combination above in order to provide temperature control of the coating process within the drum.

Allowable Subject Matter

Claims 8-10, 12-14, 23, and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 25, 26, and 28 would be allowable.

Response to Arguments

Applicants' arguments filed 11/5/08 have been fully considered but they are not persuasive.

Applicants collectively contend that the 103 rejection under the primary reference to Mohmeyer including any supplemental references combined therewith, should be withdrawn because Mohmeyer does not teach or suggest suggested a) said one end [of the drum], said other end [of the drum], and said peripheral wall as a whole configure a vessel for accommodating said granules to be processed, b) said one end and said other end are respectively provided with an air vent, one of which constitutes an air inlet for supplying process gas from outside into said rotating drum, and the other one of which constitutes an air outlet for exhausting the process gas from inside said rotating drum to the outsider when coating the granules because Mohmeyer provides for one end of the drum to be closed by a lid when coating, and c) the process gas supplied into said rotating drum through said air inlet passes through said layer of the granules inside said rotating drum and is exhausted from said air outlet.

All arguments are acknowledged but are unconvincing to warrant a grant of patentability of the instantly claimed invention as provided in claim 1. Applicants' claimed invention fails to clearly define over the prior art as evidenced by Mohmeyer and Shuri. Mohmeyer does provide for a vessel having ends, one with a lid and one without a lid and a peripheral wall defining a vessel for accommodating granules therein as shown in Fig. 1 of Mohmeyer. Also, as shown in Fig. 1, Mohmeyer provides for an air vent, one of which constitutes an air inlet (area 9) for supplying process gas from outside into said rotating drum, and the other one (area 15) of which constitutes an air outlet for exhausting the process gas from inside said rotating drum to the

outsider when coating the granules. Merely because Mohmeyer provides for one end of the drum to be closed with the lid (14) does not explicitly or implicitly suggest that the lid when closed provides an airtight seal. Thus, the lid (14) would merely act to keep the contents (i.e., granules) from falling out but yet let processing gas to pass therefrom. Finally, when the drum is filled with its contents (i.e., granules) and gas is allowed to fill the drum when the lid is placed thereon, one of ordinary skill in the art would expect the process gas supplied into said rotating drum through said air inlet to pass through the contents inside said rotating drum and be exhausted from the drum via passage through edges of the lid which would act as an air outlet.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton can be reached on (571) 272-1465. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura Edwards/
Primary Examiner
Art Unit 1792

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January 16, 2009